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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,208	12/18/2003	Daniel Kuzmich	9/272	1223
28509	7590	04/10/2006		
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P O BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER SEAMAN, D MARGARET M	
			ART UNIT 1625	PAPER NUMBER

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/739,208

Applicant(s)

KUZMICH ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1--8 (in part), drawn to compounds of formula (IA) wherein R<sup>1</sup> is phenyl, classified in various classes and subclasses, depending upon an election of a single disclosed species.
  - II. Claims 1-8 (in part), drawn to compounds of formula (IA) wherein R<sup>1</sup> is pyridine, quinoline or tetrahydroquinoline, classified class 546, subclass various depending upon an election of a single disclosed species.
  - III. Claims 1-8 (in part), drawn to compounds of formula (IA) wherein R<sup>1</sup> is dihydrobenzofuran or benzofuran, classified class 548, subclass various depending upon an election of a single disclosed species.
  - IV. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein R<sup>1</sup> is indole, dihydroindole or benzimidazole, classified class 548, subclass various depending upon an election of a single disclosed species.
  - V. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein R<sup>1</sup> is benzodioxole, classified class 549, subclass various depending upon an election of a single disclosed species.

- VI. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is dihydrobenzothienyl, benzothienyl or thienyl, classified class 548, subclass various depending upon an election of a single disclosed species.
- VII. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is benzoxazole, benzisoxazole, classified class 548, subclass various depending upon an election of a single disclosed species.
- VIII. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is benzpyrazole or pyrazinyl, classified class 548, subclass various depending upon an election of a single disclosed species.
- IX. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is tetrahydronaphthyridinone, classified class 544, subclass various depending upon an election of a single disclosed species.
- X. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is dihydrochromene, classified class 549, subclass various depending upon an election of a single disclosed species.
- XI. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is pyrimidine, classified class 544, subclass various depending upon an election of a single disclosed species.
- XII. Claims 1-3 and 5-8 (in part), drawn to compounds of formula (IA) wherein  $R^1$  is other than described, classified in various classes and subclasses depending upon an election of a single disclosed species.

- XIII. Claims 9-10, drawn to a method of modulating glucocorticoid receptor, classified in class 514, subclass various depending upon an election of one of the above groups I-XII.
- XIV. Claim 11, drawn to method of treating a disease state or condition, classified in class 514, subclass various depending upon an election of one of the above groups I-XII.
- XV. Claims 12-14, drawn to method of treating a disease, classified in class 514, subclass various depending upon an election of one of the above groups I-XII.
- XVI. Claim 15, drawn to method of treating a disease state or condition, mediated by the glucocorticoid receptor with a compound according to claims 1-7 (limited to the election of one of the above groups I-XII) and a glucocorticoid, classified in class 514, subclass various depending upon an election of a single disclosed species.
- XVII. Claims 16-21(in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is phenyl, classified in various classes and subclasses, depending upon an election of a single disclosed species.
- XVIII. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is pyridine, quinoline or tetrahydroquinoline, classified class 546, subclass various depending upon an election of a single disclosed species.

- XIX. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is dihydrobenzofuran or benzofuran, classified class 548, subclass various depending upon an election of a single disclosed species.
- XX. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is indole, dihydroindole or benzimidazole, classified class 548, subclass various depending upon an election of a single disclosed species.
- XXI. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is benzodioxole, classified class 549, subclass various depending upon an election of a single disclosed species.
- XXII. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is dihydrobenzothienyl, benzothienyl or thienyl, classified class 548, subclass various depending upon an election of a single disclosed species.
- XXIII. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is benzoxazole, benzisoxazole, classified class 548, subclass various depending upon an election of a single disclosed species.
- XXIV. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is benzpyrazole or pyrazinyl, classified class 548, subclass various depending upon an election of a single disclosed species.
- XXV. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is tetrahydronaphthyridinone, classified class 544, subclass various depending upon an election of a single disclosed species.

- XXVI. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is dihydrochromene, classified class 549, subclass various depending upon an election of a single disclosed species.
- XXVII. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is pyrimidine, classified class 544, subclass various depending upon an election of a single disclosed species.
- XXVIII. Claims 16-21 (in part), drawn to compounds of formula (IB) wherein R<sup>1</sup> is other than described, classified in various classes and subclasses depending upon an election of a single disclosed species.
- XXIX. Claims 22-23, drawn to a method of modulating glucocorticoid receptor, classified in class 514, subclass various depending upon an election of one of the above groups XVII-XXVIII.
- XXX. Claim 24, drawn to method of treating a disease state or condition, classified in class 514, subclass various depending upon an election of one of the above groups XVII-XXVIII.
- XXXI. Claims 25-27, drawn to method of treating a disease, classified in class 514, subclass various depending upon an election of one of the above groups XVII-XXVIII.
- XXXII. Claim 28, drawn to method of treating a disease state or condition mediated by the glucocorticoid receptor with a compound according to claims 16-21 (limited to the election of one of the above groups XVII-

XXVIII) and a glucocorticoid, classified in class 514, subclass various depending upon an election of species.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-XII and XVII-XXVIII are related as products which share an alleged common utility of glucocorticoid receptor mediation function but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products as claimed can be used to perform another utility such as angiotensin II inhibition.

Inventions I-XII and XIII-XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating hypertension can be practiced with another materially different product such as aspirin.

Inventions XVII-XXVIII and XXIX - XXXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be



shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process of treating hypertension can be practiced with another materially different product such as aspirin.

3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

4. A telephone call was made to Timothy Witkowski on 4/4/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.


Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms